

Notice of Allowability

Application No.

09/700,712

Examiner

S. Devi, Ph.D.

Applicant(s)

CARLIN ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' amendment filed 01/16/07.
2. ☒ The allowed claim(s) ~~is/are~~ claims 30-37, now renumbered as claims 1-8 respectively.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

ATTACHMENT TO NOTICE OF ALLOWABILITY

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 01/16/07 in response to the non-final Office Action mailed 09/13/06.

Examiner's Amendment

- 2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Mr. Scott Brairton in a telephonic interview on 02 April 2007.

This application has been amended as indicated below.

- (a) Claims 17-29 have been canceled.

- (b) New claims 30-37 have been added as indicated below:

--Claim 30 (New). A $\Delta thyA$ strain of *Vibrio cholerae* lacking the functionality of its *thyA* gene located in the chromosome of said strain due to site-directed deletion and/or insertion of nucleotides in the *thyA* gene, said *thyA* gene consisting of the nucleotide sequence of SEQ ID NO: 1.

Claim 31 (New). The $\Delta thyA$ strain of *Vibrio cholerae* of claim 30, wherein said strain comprises at least one episomal autonomously replicating DNA element having a functional *thyA* gene that enables the strain to grow in the absence of thymine in a growth medium, wherein the at least one episomal autonomously replicating DNA element further comprises a structural gene encoding a homologous or heterologous protein.

Claim 32 (New). The $\Delta thyA$ strain of *Vibrio cholerae* of claim 31, wherein the at least one episomal autonomously replicating DNA element is a plasmid.

Claim 33 (New). The $\Delta thyA$ strain of *Vibrio cholerae* of claim 31, wherein the functional *thyA* gene is a foreign *thyA* gene.

Claim 34 (New). The $\Delta thyA$ strain of *Vibrio cholerae* of claim 33, wherein the foreign *thyA* gene is *Escherichia coli thyA* gene.

Claim 35 (New). The $\Delta thyA$ strain of *Vibrio cholerae* of claim 31, wherein the encoded heterologous protein is selected from the group consisting of heat-labile enterotoxin B-subunit of *Escherichia coli* (LTB) and *Schistosoma japonicum* glutathione S-transferase 26 kD protein (GST 26 kD).

Claim 36 (New). The $\Delta thyA$ strain of *Vibrio cholerae* of claim 30, wherein the insertion is of a kanamycin resistance gene into *pstI* site in the *thyA* gene in the form of a Kan^R geneblock.

Claim 37 (New). The $\Delta thyA$ strain of *Vibrio cholerae* of claim 36, wherein 209 base pairs from said *thyA* gene upstream of the insertion site and 261 basepairs from the Kan^R geneblock have been deleted.--

Status of Claims

3) Claims 17, 18, 20 and 23-27 have been amended via the amendment filed 01/16/07.

Claims 17-29 have been canceled via this Examiner's amendment.

New claims 30-37 have been added via this Examiner's amendment.

Claims 30-37 are pending and are under examination.

Objection(s) Moot

4) The objection to claim 23 made in paragraph 20(b) of the Office Action mailed 07/01/05 and maintained in paragraph 7 of the Office Action mailed 09/13/06 is moot in light of the cancellation of the claim.

Rejection(s) Moot

5) The rejection of claim 17 and claims 19-23 and 26-29 that depend therefrom, made in paragraph 16 of the Office Action mailed 09/13/06 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is moot in light of the cancellation of the claims.

6) The rejection of claim 24 made in paragraph 17 of the Office Action mailed 09/13/06 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is moot in light of the cancellation of the claim.

7) The rejection of claims 25, 26 and those dependent therefrom made in paragraph 18 of the Office Action mailed 09/13/06 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is withdrawn in light of the cancellation of the claims.

- 8)** The rejection of claims 17-29 made in paragraph 19 of the Office Action mailed 09/13/06 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the deposit issue, is moot in light of the cancellation of the claims.
- 9)** The rejection of claim 24 made in paragraph 20(a) of the Office Action mailed 09/13/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claim.
- 10)** The rejection of claim 24 made in paragraph 20(b) of the Office Action mailed 09/13/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claim.
- 11)** The rejection of claim 25 made in paragraph 20(c) of the Office Action mailed 09/13/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claim.
- 12)** The rejection of claim 26 made in paragraph 20(d) of the Office Action mailed 09/13/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claim.
- 13)** The rejection of claim 24 made in paragraph 20(e) of the Office Action mailed 09/13/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claim.
- 14)** The rejection of claim 17 made in paragraph 20(f) of the Office Action mailed 09/13/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claim.
- 15)** The rejection of claim 18 made in paragraph 20(g) of the Office Action mailed 09/13/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claim.
- 16)** The rejection of claim 20 made in paragraph 20(h) of the Office Action mailed 09/13/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claim.
- 17)** The rejection of claim 24 made in paragraph 20(i) of the Office Action mailed 09/13/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation

of the claim.

18) The rejection of claims 19-29 made in paragraph 20(j) of the Office Action mailed 09/13/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.

19) The rejection of claims 17-19 made in paragraph 21 of the Office Action mailed 09/13/06 under 35 U.S.C. § 102(b) as being anticipated by Valle *et al.* (*Infect. Immun.* 68: 6411-6418, 01 November 2000), is moot in light of the cancellation of the claims.

Relevant Prior Art

20) The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

- Mahan *et al.* (US 5,434,065) disclosed the *Vibrio cholerae* thyA deficient strain, MT173, comprising the pIVET2 vector introduced therein, which vector contains *E. coli* thyA-lac fusion. See Example 2.

Remarks

21) Claims 30-37, now renumbered as claims 1-8 respectively, are allowed.

Claims 30-37 have descriptive support in the originally filed claims, canceled claims 17-29, Figures, last full paragraph on page 9 and pages 6 and 14 of the specification.

22) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

23) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

24) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be

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reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

April, 2007



S. DEVI, PH.D.
PRIMARY EXAMINER